



Medical Marijuana Advisory Board Meeting

**Wednesday, April 12, 2023
10:30am – 12:30pm**

MMAB Agenda

- I. Call meeting to order, roll call and introduction of Board members
- II. Approval of the previous meeting's minutes – Nov. 22, 2022
- III. Program Update
- IV. Old Business
 - a. Chronic Hepatitis C Addition
- V. New Business
 - a. Subcommittee duties, assignments and updates:
 - i. Medical Review – Vacant, Subcommittee Chair
 - ii. Patient and Caregiver – Shalawn James, Subcommittee Chair
 - iii. Regulatory Review – Christine Roussel, Pharm.D., R.Ph., Subcommittee Chair
 - iv. Medical Research – Bhavini Patel, Subcommittee Chair
 - Vote on findings and recommendations for Research Initiative presented by Organic Remedies at July Board meeting
 - b. 2023 Board Meetings
- VI. Additional Discussion/Q&A
- VII. Adjournment

Medical Marijuana Program Update

- 7-year Anniversary of Bill Signing
- Upcoming Research Summit
- Medical Marijuana Assistance Program
- Program Metrics
- Patient Purchasing Activity
- Permittee Pricing Trends

Medical Marijuana Program Update

Medical Marijuana Assistance Program (MMAP)

Medical Marijuana Program Update

MMAP Implementation Update

	Full Cost	Current Cost After Benefits	MMAP Phase 1	MMAP Phase 2	MMAP Phase 3 Pilot	MMAP Phase 3 Expansion
MM Identification Card	\$50.00	\$25.00 <i>50% discount</i>	No Cost	No Cost	Implemented November 14, 2022!	
Caregiver Background Checks	\$20.85	\$7.60 <i>65% discount</i>	Implemented March 1, 2022!			
Patient Product Cost	Retail Price				\$50/month <i>For PACE/PACENET Patients</i>	<i>Timing, patient applicability, and monthly benefit amount dependent on future funding</i>

[35 P.S. Section 10231.902](#)

Medical Marijuana Program Update

MMAP Phase 3 Pilot Update:

- \$50 monthly benefit provided to medical marijuana patients also enrolled in PACE/PACENET to apply toward the cost of medication.
- More than 1,100 transactions
- Nearly \$65k granted to patients

Medical Marijuana Program Update

Program Metrics

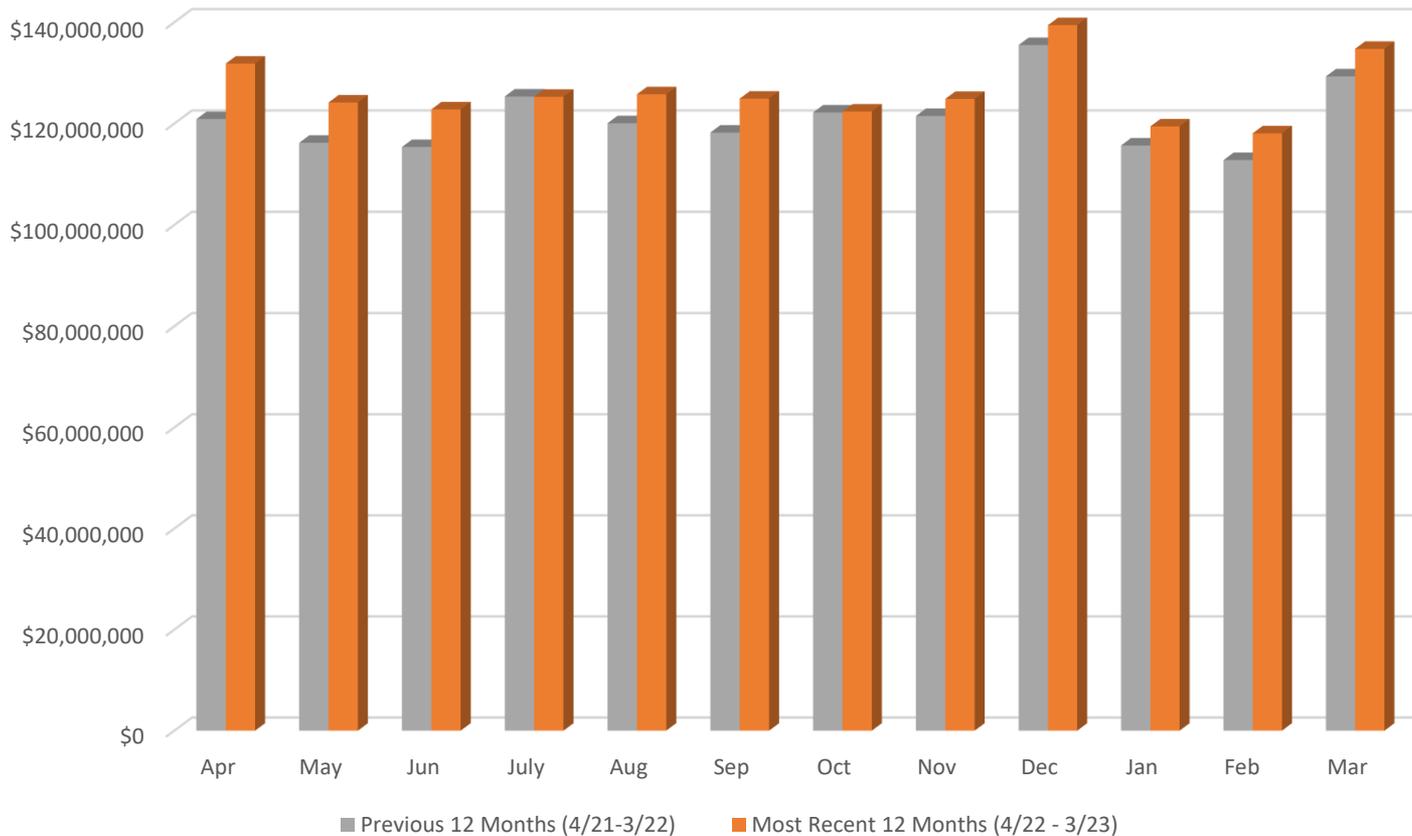
Medical Marijuana Program Update

- Program to date:
 - 898,992 Patients and Caregivers Registered;
 - 425,367 Active Patient Certifications;
 - 1,825 Approved Practitioners;
 - 31 Million Patient Dispensing Events;
 - 87.9 Million Products Dispensed
 - \$7.3 Billion in Total Sales;
 - \$2.9 Billion by G/Ps to Dispensaries; and
 - \$4.4 Billion by Dispensaries
 - 173 Operational Dispensaries

*As of 3/30/23

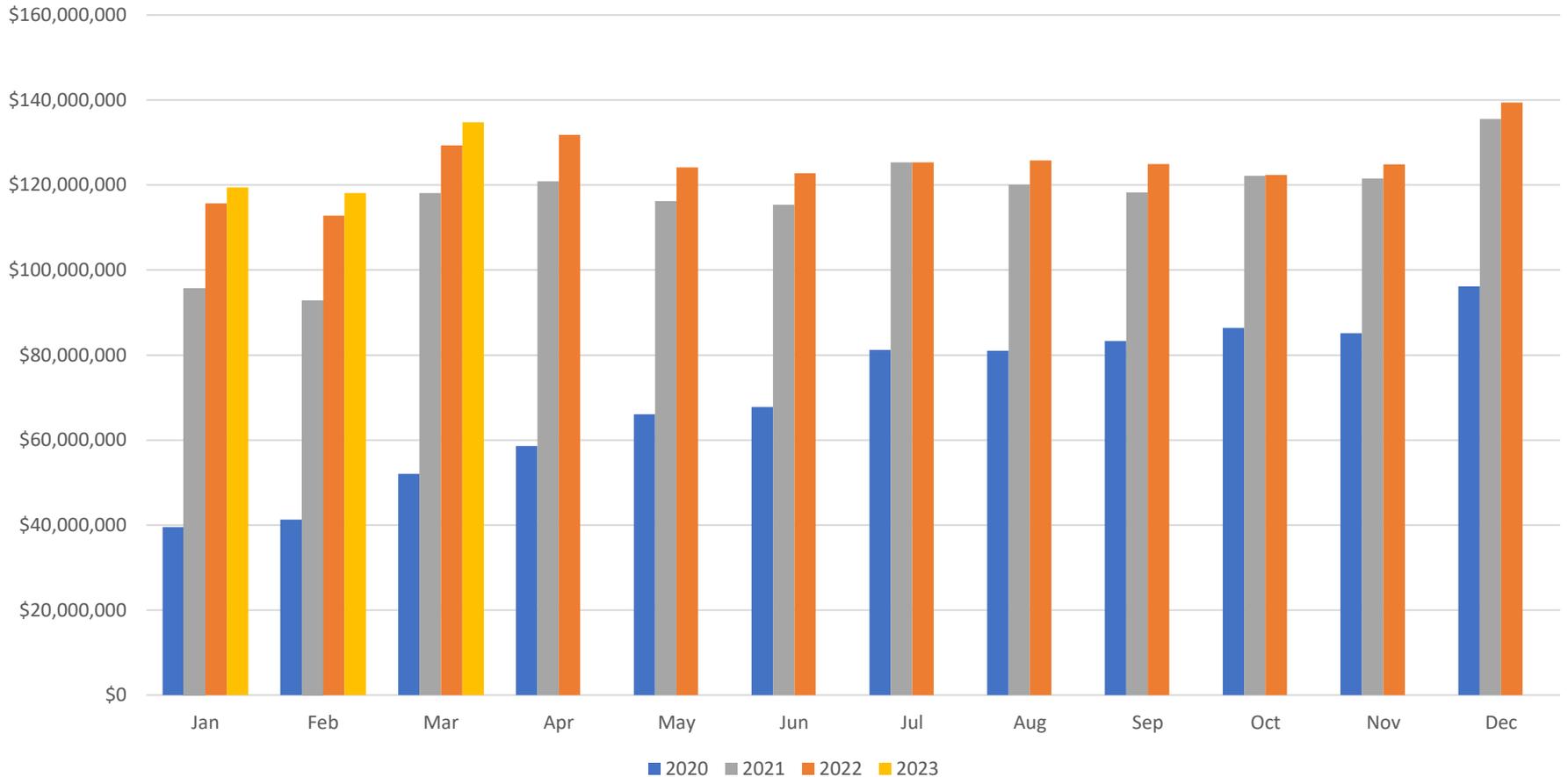
Medical Marijuana Program Update

Month on Month Dispensary Sales



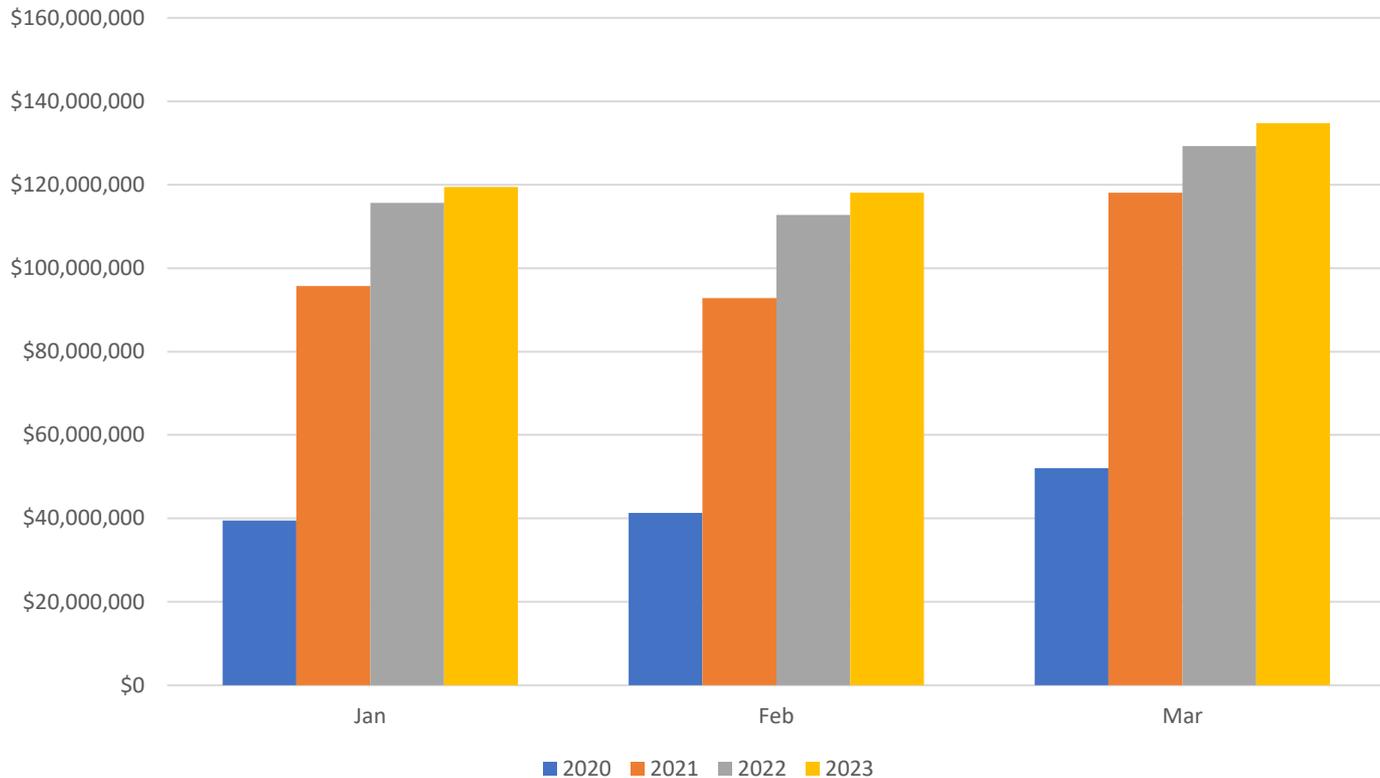
Medical Marijuana Program Update

Dispensary Sales by Month Since Jan 2020



Medical Marijuana Program Update

Year on Year Dispensary Sales for January, February, and March

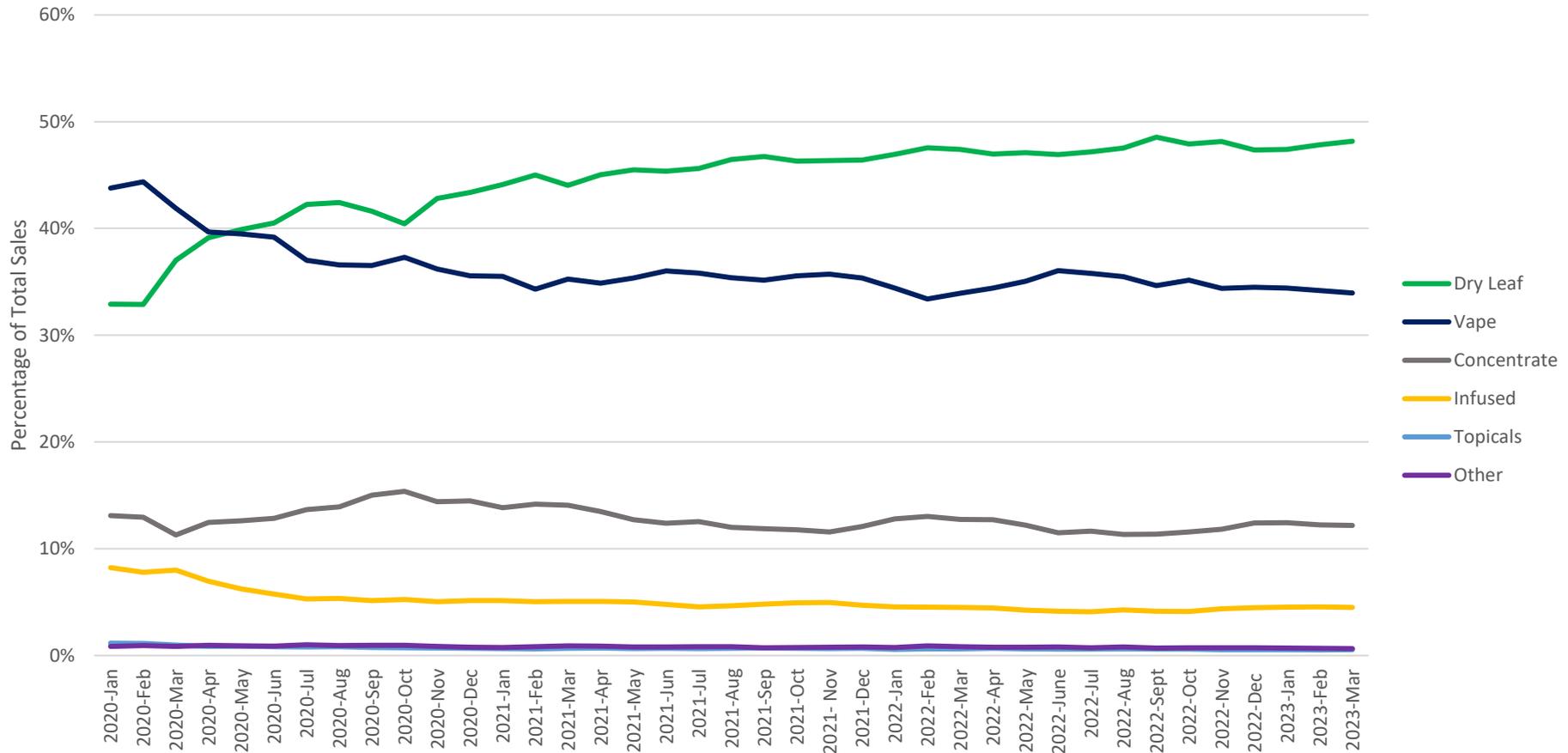


Medical Marijuana Program Update

Program Metrics: Permittee Pricing Trends

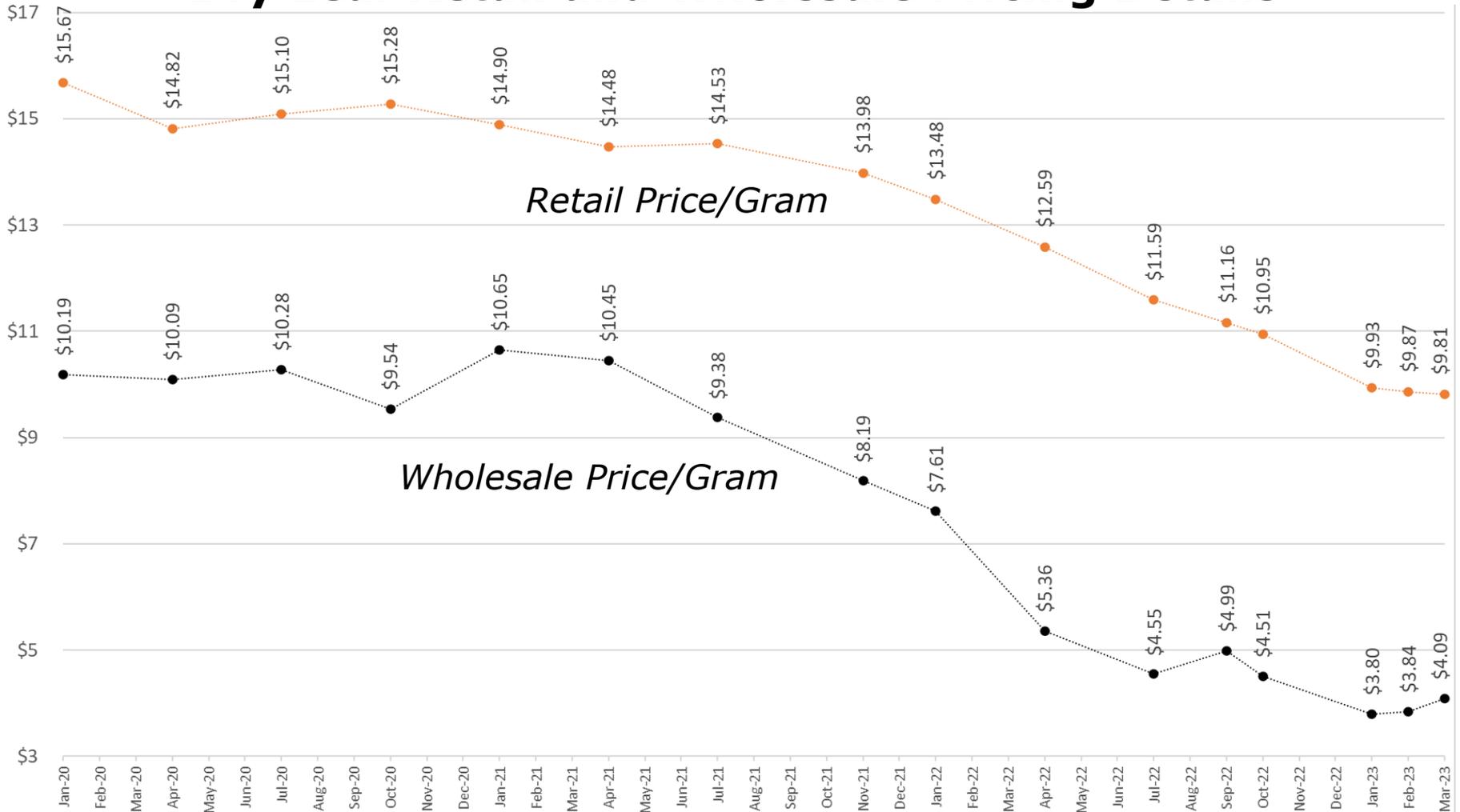
Medical Marijuana Program Update

Patient Purchasing Trends by Product Category



Medical Marijuana Program Update

Dry Leaf Retail and Wholesale Pricing Details



Medical Marijuana Program Update



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MMAB Duties

According to 35 P.S. § 10231.1201(j) the Medical Marijuana Advisory Board shall have the following duties:

- (1) To examine and analyze the statutory and regulatory law relating to medical marijuana within this Commonwealth.
- (2) To examine and analyze the law and events in other states and the nation with respect to medical marijuana.
- (3) To accept and review written comments from individuals and organizations about medical marijuana.
- (4) To issue written reports to the Governor, the Senate and the House of Representatives.

Subcommittee Assignments

Medical Review – Modify Types of Conditions

Patient and Caregiver – Affordable Access

Regulatory Review – Medical Professional Type

Medical Research – Form of Medical Marijuana

Subcommittee Updates

- **Medical Review** – *Vacant*, Subcommittee Chair
- **Patient and Caregiver** – Shalawn James, Subcommittee Chair
- **Regulatory Review** – Christine Roussel, Pharm.D., R.Ph. Subcommittee Chair
- **Medical Research** – Bhavini Patel, Subcommittee Chair
 - Findings and recommendations for Research Initiative presented at July 28th Board Meeting

Medical Research Subcommittee Research Initiative Presentation

Request

- Presented at Medical Marijuana Advisory Board Meeting on Thursday, July 28, 2022
- Presentation: An Analysis of the Efficacy of Organic Remedies Inc. Manufacturing Infrastructure for the Production of Sterile Extracts Derived from Contaminated Feed Stock
- The research study involved evaluating the effectiveness of solvent-based extraction methods and processes for eliminating or substantially diminishing microbial contamination from feed materials (i.e., marijuana plant) during the extraction process.
- Request - Amend the Act to Allow Cannabis Product Remediation when products exceed microbial contamination thresholds
- Reviewed through the Subcommittee on Medical Research which convened on two separate occasions

Recommendation of Medical Research Subcommittee

- Medical Research Subcommittee evaluated the data during two consecutive meetings and reached consensus
- Recommendation: In the interest of patient safety, at this time, do NOT recommend to change the PA DOH regulations on allowable qualities of colony forming units of:
 - bacteria
 - total yeast and fungus

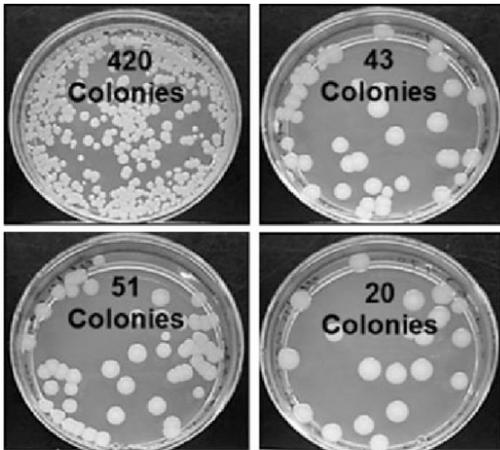
How are bacteria, yeast and fungus measure in cannabis?

Background and Terminology

Microorganisms are often measures as colony forming units (CFU). It is a **measure of viable** of cells that can proliferate / grow to form small colonies.

In cannabis we use the term colony forming units per gram of harvested cannabis plant material or final product

Term expressed in regulatory documents = Colony forming units / gram of cannabis (aka cfu/gram)



Numbers Represent
Increasing Amounts of
Bacteria / Fungus
Allowed in each Gram
of Cannabis



$$\begin{aligned} 10 \times 6 &= 10^6 = 1,000,000 \\ 10 \times 5 &= 10^5 = 100,000 \\ 10 \times 4 &= 10^4 = 10,000 \\ 10 \times 3 &= 10^3 = 1,000 \\ 10 \times 2 &= 10^2 = 100 \\ 10 \times 1 &= 10^1 = 10 \end{aligned}$$



Most Permissive aka Lenient

Not Permissive aka Strict

Gram of Cannabis ~ size of Grape

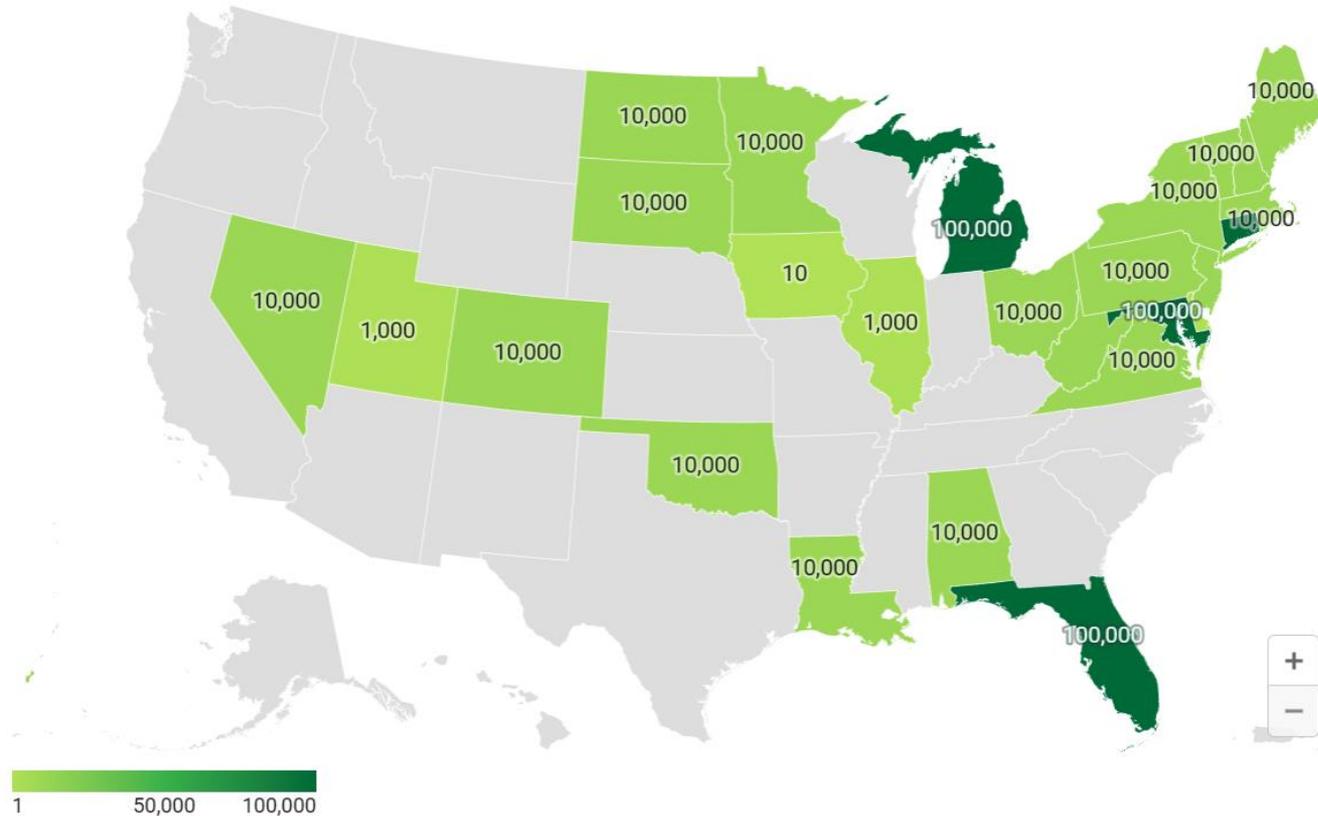
Pennsylvania DOH Office of Medical Marijuana: Guidance for Quality Testing and Sampling by Approved Laboratories

Microbials			
Water Activity	A _w 0.65	Not required for fresh frozen samples.	Dutch Office of Medical Cannabis
Moisture Content	Between 5-15%		
Salmonella	Absence in 1g	<p>Microbial testing required for every harvest and process lot.</p> <p>A result higher than 1000 CFU/g will prompt an alert and review by the Department.</p> <p>A result higher than 100 CFU/g will prompt an alert and review by the Department.</p>	<p>American Herbal Pharmacopeia Cannabis Inflorescence</p>
E. Coli	Absence in 1g		
Mold and Yeast	<ul style="list-style-type: none"> • 10,000 CFU/g Harvest Lot • 1000 CFU/g Process Lot • 10,000 CFU/g Final processed flower at product testing 		
Total Viable Aerobic Bacteria Microbial Count	<ul style="list-style-type: none"> • 10,000 CFU/g Harvest Lot • 10,000 CFU/g Process Lot (including flower at product testing) 		
Bile tolerant gram-negative bacteria	<ul style="list-style-type: none"> • 1000 CFU/g Harvest Lot • 100 CFU/g Process Lot • 1000 CFU/g Final flower at product testing 		

<https://www.health.pa.gov/topics/Documents/Programs/Medical%20Marijuana/2018.8.10%20MM%20-%20Updated%20Guidance%20for%20Quality%20Testing%20and%20Sampling%20by%20Approved%20Laboratories.pdf>
Medical Research Subcommittee Presentation

Total Yeast and Mold Microbial Cannabis Testing By State

Expressed in colony forming units / gram of cannabis



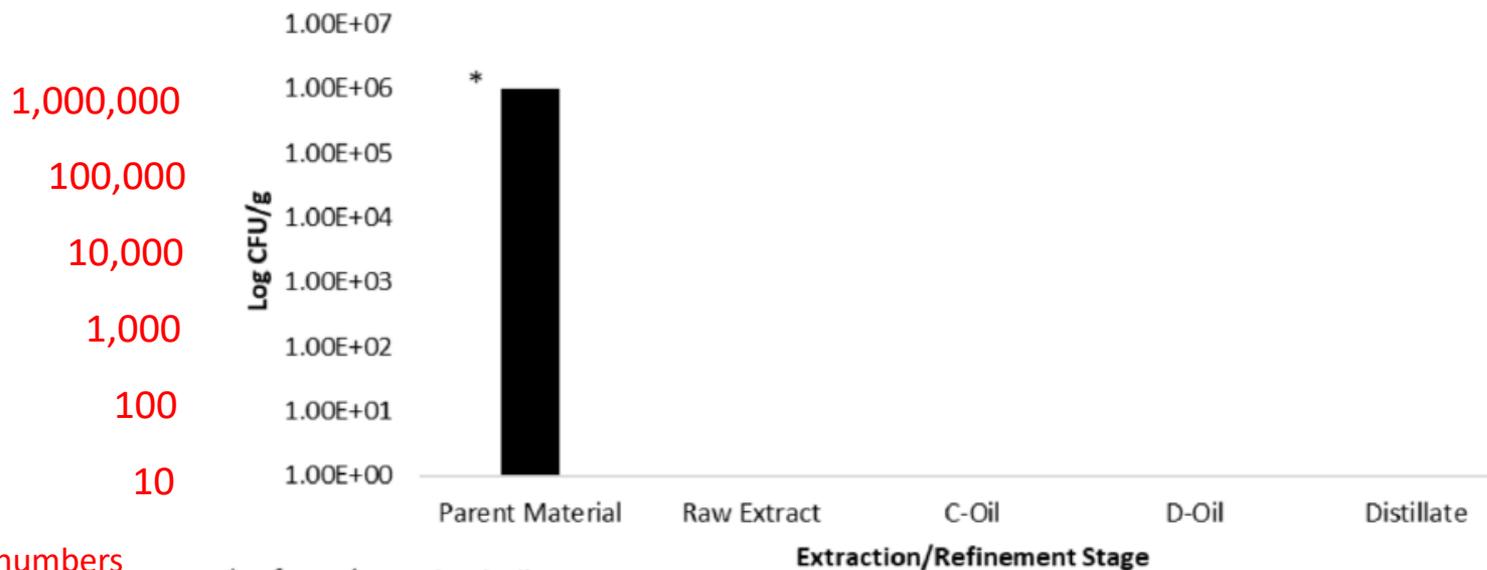
[Cannabis Microbial Testing Regulations by State - Medicinal Genomics](#)

This chart was last updated March 1, 2023

Map: Medicinal Genomics • Source: Medicinal Genomics • Created with Datawrapper

An Analysis of the Efficacy of Organic Remedies Inc. Manufacturing Infrastructure for the Production of Sterile Extracts Derived from Contaminated Feed Stock

Total Yeast and Mold By Stage



Whole numbers inserted for ease of interpretation
Note – chart is a logarithmic expression

**10⁶ CFU/g used to indicate TNTC*

Considerations

- The reproducibility of the results. The study highlights brand name and proprietary methods
- Use of source material where the mold and yeast were “too numerous to count” ~ 1,000,000 CFU / gram *used prior to remediation. The starting product represents a level that is 100 times greater than the maximum acceptable level allowed by PA*
- In Review of other states, PA microbial thresholds are within the normal distribution, and on neither end of the extremes. (35th percentile)
- Remediation is allowed in some states, but for our purposes we should consider what is acceptable to remediate. States like California, a remediation plan needs to be submitted and approved by the Board. Could in PA our regulations be sufficiently details to make it clear when remediation is acceptable?

Herbal Medicines Compendium

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[About this Compendium](#) [Monographs](#) [General Chapters](#) [General Notices/Resources](#)

Search Monographs

Home » Monographs » Proposed For Comment » Cannabis Species Inflorescence

Cannabis Species Inflorescence

Proposed For Comment Version 0.1

*Cannabis Species Inflorescence*¹

Key Information

- **LATEST VERSION:**
Proposed For Comment
Version 0.1
- Posted on Sep 21, 2022
-  Visual
Representation of
Chromatographic

It's time to hold cannabinoid products to the highest standard:
USP Cannabis Panel statement
on delta8-THC



<https://www.usp.org/dietary-supplements-herbal-medicines/cannabis>

Cannabis Species Inflorescence Proposed For Comment Version 0.1. Herbal Medicines Compendium. Sep 21, 2022. <https://hmc.usp.org/monographs/cannabis-species-inflorescence-0-1>

Limits for Contaminants

The limits for contaminants in cannabis — including pesticide residues, microbial load, aflatoxin levels, and elemental contaminants — should be based on scientific considerations. The USP *JNP* article provides appropriate tests, also contained in USP General Chapters and criteria to control contaminants and which may be useful for quality assurance.

- **USP General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests**
- **USP General Chapter <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms**
- **USP General Chapter <232> Elemental Impurities—Limits**
- **USP General Chapter <561> Articles of Botanical Origin: Pesticide Residue Analysis; Test for Aflatoxins**
- **USP General Chapter <1111> Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use: Microbial limits for products that conform to limits for inhalation use.**

Highlights from the Proposed USP Cannabis Monograph

Treat Cannabis as a single highly variable species

THC:CBD Ratio – Establishing Formal Order of Expression

List the labeled amount of all cannabinoids measured (mg/g) where contents is NLT 80% and NMT 120% of the labeled amount.

Labelling Standards

Microbial Contamination Limits



Definitions of THC dominant, CBD dominant and Intermediate chemotypes

Products must be labelled if they have undergone microbial remediation

Table 4. Proposed Acceptance Criteria for Microbial Contamination¹ 
Microbial Enumeration Tests <61>: <ul style="list-style-type: none"> total aerobic bacterial count is NMT 10⁵ cfu/g (100,000 cfu/g) total combined molds and yeasts count is NMT 10⁴ cfu/g (10,000 cfu/g)
Microbial Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use <1111>: <ul style="list-style-type: none"> These stringent requirements are intended for products labeled to indicate to healthcare practitioners and patients that such products (particularly for inhalation products) have a reduced microbial load. total aerobic bacterial count is NMT 10² cfu/g (100 cfu/g) total combined molds and yeasts count is NMT 10¹ cfu/g (10 cfu/g) It meets the requirements of the tests for absence of total bile-tolerant Gram-negative bacteria, <i>Salmonella</i> species, <i>Escherichia coli</i>, <i>Staphylococcus aureus</i>, and <i>Pseudomonas aeruginosa</i>.
Tests for Specified Microorganisms <62>: <ul style="list-style-type: none"> total bile-tolerant Gram-negative bacteria does not exceed 10³ cfu/g (1,000 cfu/g) meets requirements of tests for absence of <i>Salmonella</i> species and <i>Escherichia coli</i>.
cfu/g, colony forming units of microorganism per gram of cannabis material; NMT, not more than.

USP < 61 > Microbial Testing
 Total Aerobic Bacteria Count < 100,000 cfu/gram
 Total Combined Yeast and Mold < 10,000 cfu/gram

USP <1111> Acceptance Criteria Non-Sterile Products
 Total Aerobic Bacteria Count < 100 cfu/gram
 Total Combined Yeast and Mold < 10 cfu/gram

[USP, FDA Propose Quality Standards for Cannabis, Highlighting its Role as Medicine \(pharmacytimes.com\)](https://www.fda.gov/oc/2022/09/21-usp-fda-propose-quality-standards-for-cannabis-highlighting-its-role-as-medicine); Cannabis Species Inflorescence Proposed For Comment Version 0.1. Herbal Medicines Compendium. Sep 21, 2022. <https://hmc.usp.org/monographs/cannabis-species-inflorescence-0-1>

Recommendation of Medical Research Subcommittee

- Recommendation: In the interest of patient safety, at this time, do NOT recommend to change the PA DOH regulations on allowable qualities of colony forming units of:
 - bacteria
 - total yeast and fungus
- The subcommittee does recommendation an evaluation of PA's regulations on cannabis product testing when the USP Cannabis monograph has been finalized
- While state regulation is heterogeneous, Pennsylvania regulation is currently with the ranges of other states
- US Pharmacopeia Cannabis Monograph has been published and closed for comments in 2022.

MMAB Meeting

- Additional Discussion/Q&A
- 2023 Board Meetings

Dates:

- ▣ June 28th
- ▣ September 6th
- ▣ November 15th

Time:

10:30am – 12:30pm